Applicant(s): P. Bonutti Application No.: 10/722,102 Examiner: P. Philogene

## Amendments to the Claims:

1. (Currently amended) A method of replacing at least a portion of a patient's knee, the method comprising the steps of:

making an incision in a knee portion of a leg of the patient sized smaller than the portion of the knee to be replaced;

expanding the incision from an unexpanded configuration to an expanded configuration by applying force against opposite edge portions of the incision;

determining a position of a cutting guide using references derived independently from an intramedullary device;

positioning a cutting guide using the determined position, passing the cutting guide through the expanded incision and on a surface of a distal end portion of an unresected femur, the cutting guide secured to the bone free of an extramedullary or intramedullary alignment rod, the cutting guide sized to be received in the expanded configuration;

moving a cutting tool through the incision into engagement with a guide surface on the cutting guide; and

forming at least an initial cut on the femur by moving the cutting tool along the guide surface:

attaching a replacement portion of the knee to the cut surface, the replacement portion having a transverse dimension that is larger than a transverse dimension of the guide surface.

- (Previously presented) The method of claim 1 wherein the surface is a medial or lateral side of the distal end portion of the femur.
  - 3. (Canceled)
- (Previously presented) The method of claim 1 wherein a computer navigation system is used in the determining step.
  - 5. (Original) The method of claim 1 wherein the positioning step includes removably

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attaching the cutting guide to the side surface of the distal end portion of the femur.

6. (Original) The method of claim 5 wherein the cutting guide is removably attached with first and second pins extending through holes in the cutting guide and into the femur.

7. (Original) The method of claim 1 wherein the guide surface comprises a plurality of straight guide segments.

8. (Original) The method of claim 7 wherein the plurality of straight guide segments comprises:

a distal guide segment disposed in a plane which extends perpendicular to a longitudinal central axis of the femur and extends through lateral and medial condyles of the femur;

an anterior chamfer guide segment disposed in a plane which extends at an acute angle to a plane containing the distal guide surface;

a posterior chamfer guide segment disposed in a plane which extends at an acute angle to a plane containing the distal guide surface, the plane containing the posterior chamfer guide surface extending perpendicular to the plane containing the anterior chamfer guide surface;

an anterior guide segment disposed in a plane which extends perpendicular to a plane containing the distal guide surface and extends generally parallel to a longitudinal central axis of the femur; and

a posterior guide surface disposed in a plane which extends parallel to a plane containing the anterior guide surface and perpendicular to a plane containing the distal guide surface.

## 9. (Canceled)

10. (Original) The method of claim 1 wherein said step of cutting the femur includes utilizing the guide surface on the cutting guide to guide the cutting tool during making of an initial portion of a cut in the femur, and completing the cut in the femur while guiding the cutting tool with a surface formed during making of the initial portion of the cut in the femur.

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11. (Canceled)

12. (Previously presented) The method of claim 10 wherein the cutting guide is removed

from a side surface of the distal end portion of the femur after making the initial portion of the

cut and before completion of the cut.

13-18. (Canceled)

19. (Currently amended) A method of replacing at least a portion of a joint in a patient, the

method comprising the steps of:

obtaining a customized cutting guide fabricated for the patient based on preoperative and

elinical information, the cutting guide positionable in a pre-determined position on a bone of the

joint using references derived independently from an intramedullary device;

making an incision proximal adjacent to the joint in the patient, the incision sized smaller

than the portion of the joint to be replaced;

determining a position of a cutting guide using references derived independently from an

intramedullary device;

positioning the cutting guide using in the pre-determined position[[,]] by passing the cutting

guide through the incision and on a surface of an end portion of an unresected bone of the joint;

moving a cutting tool through the incision into engagement with a guide surface on the

positioned cutting guide;

cutting the unresected bone of the joint for the first time, by moving the cutting tool along

the guide surface;

attaching a replacement portion of the knee to the cut surface, the replacement portion

having a transverse dimension that is larger than a transverse dimension of the guide surface; and

disposing of the cutting guide, as it is no longer safely usable or useful in a subsequent

procedure, the cutting guide having been contaminated, or the bone for which it was custom

fabricated having been cut and therefore changed.

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 (Previously presented) The method of claim 19 wherein the side surface is a medial or lateral side of the end portion of the first bone.

21-22, (Canceled)

23. (Original) The method of claim 19 wherein the positioning step includes removably attaching the cutting guide to the side surface of the end portion of the first bone.

24. (Original) The method of claim 23 wherein the cutting guide is removably attached with first and second pins extending through holes in the cutting guide and into the first bone.

25. (Original) The method of claim 19 wherein the guide surface comprises a plurality of straight guide segments.

26. (Original) The method of claim 25 wherein the plurality of straight guide segments comprises:

a distal guide segment disposed in a plane which extends perpendicular to a longitudinal central axis of the first bone;

an anterior chamfer guide segment disposed in a plane which extends at an acute angle to a plane containing the distal guide surface;

a posterior chamfer guide segment disposed in a plane which extends at an acute angle to a plane containing the distal guide surface, the plane containing the posterior chamfer guide surface extending perpendicular to the plane containing the anterior chamfer guide surface;

an anterior guide segment disposed in a plane which extends perpendicular to a plane containing the distal guide surface and extends generally parallel to a longitudinal central axis of the first bone; and

a posterior guide surface disposed in a plane which extends parallel to a plane containing the anterior guide surface and perpendicular to a plane containing the distal guide surface.

27. (Canceled)

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28. (Original) The method of claim 19 wherein said step of cutting the first bone includes

utilizing the guide surface on the cutting guide to guide the cutting tool during making of an

initial portion of a cut in the first bone, and completing the cut in the first bone while guiding the

cutting tool with a surface formed during making of the initial portion of the cut in the first bone.

29. (Original) The method of claim 28 wherein the cutting guide is positioned on the side

surface of the end portion of the first bone during completion of the cut.

30. (Original) The method of claim 29 wherein the cutting guide is removed from the side

surface of the end portion of the first bone after making the initial portion of the cut and before

completion of the cut.

31-32. (Canceled)

33. (Previously presented) The method of claim 1, wherein in said step of making an

incision, said incision is offset from the center of said knee area.

34. (Canceled)

35. (Previously presented) The method of claim 19, wherein after said step of cutting,

further including the steps of:

removing said cutting guide; and,

guiding said cutting tool using cuts formed in said cutting step to complete said cuts.

36. (Previously presented) The method of claim 19, wherein in said step of positioning,

said cutting guide is sized smaller than said side surface.

37. (Previously presented) The method of claim 19, wherein after said step of positioning,

further including the step of:

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aligning said cutting guide using markings on said side surface.

38-39. (Canceled)

40. (Previously presented) The method of claim 1, wherein the determining step includes

adjusting the determined position to correct a deformity of the joint,

41. (Previously presented) The method of claim 1, wherein the portion of a patient's knee

replaced is at least a portion of an articulating surface of the joint.

42. (Canceled)

43. (Previously presented) A method of replacing at least a portion of a patient's knee, the

method comprising the steps of:

making an incision in a knee portion of a leg of the patient;

expanding the incision from an unexpanded configuration to an expanded configuration by

applying force against opposite edge portions of the incision;

determining a position of a cutting guide using references derived independently from an

intramedullary device;

positioning a cutting guide using the determined position, passing the cutting guide through the expanded incision and on a surface of a distal end portion of an unresected bone, the cutting

guide secured to the bone free of an extramedullary or intramedullary alignment rod, the cutting guide sized to be received in the expanded configuration;

moving a cutting tool through the incision into engagement with a guide surface on the

cutting guide; and

forming at least an initial cut on the bone by moving the cutting tool along the guide

surface;

attaching a replacement portion of the knee to the cut surface, the replacement portion

having a transverse dimension that is larger than a transverse dimension of the guide surface.

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44. (Previously presented) The method of claim 43, wherein the cutting guide is customized to a patient's bone, and further including the step of disposing of the cutting guide, as the cutting guide is no longer useful as the bone for which it has been customized has been cut

and thereby changed.

45. (Previously presented) The method of claim 43, wherein the cutting guide is fabricated

from a plurality of cutting guide parts, and further including the step of disposing of at least one

of said plurality of cutting guide parts.

46. (Previously presented) The method of claim 43, wherein the replacement portion of the

knee is attached without dislocating the knee joint.

47. (Previously presented) The method of claim 43, wherein the bone is cut with a mill.

48. (Previously presented) The method of claim 43, wherein the bone is cut using a robotic

arm.

49. (Previously presented) The method of claim 43, wherein in said forming step, a recess

is formed in the bone, and in said attaching step, at least a part of the replacement portion is

inlaid into the recess.

50. (Previously presented) The method of claim 43, wherein the replacement portion of the

knee includes a plurality of segments having an articulating surface.

51. (Previously presented) The method of claim 43, further including the step of inserting

a guide wire in bone of the knee, and wherein the replacement portion of the knee is provided

with an opening through which the guide wire is passed.

52. (Previously presented) The method of claim 43, wherein the guide surface operates to

capture the cutting tool within a slot.

53. (Previously presented) The method of claim 43, wherein at least a portion of the cutting guide is polymeric.

54. (Previously presented) The method of claim 43, wherein in carrying out the method, the quadriceps mechanism is not cut.

55. (Previously presented) The method of claim 43, wherein in carrying out the method, the articulating surface of the patella is maintained facing the femur.

56. (Previously presented) The method of claim 43, further including the step of unpacking a sterile package containing only one cutting guide.

57. (Previously presented) The method of claim 43, further including the step of unpacking a sterile package containing only one each of a cutting guide and a replacement portion of the knee.

58. (Currently amended) A method of replacing at least a portion of a joint in a patient, the method comprising the steps of:

determining a position for <u>obtaining</u> an alignment guide <u>positionable on a bone</u> using references derived independently of an intramedullary device, wherein the alignment guide is custom fabricated for the patient based on patient imaging information;

positioning the alignment guide using the determined position in relation to the surface of an unresected bone of the joint;

referencing a cutting guide with respect to the alignment guide; and

cutting the unresected bone of the joint for the first time, by moving a cutting tool along a guide surface of the cutting guide.

59. (Previously presented) The method of claim 58, wherein the joint is a knee joint and a

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total knee replacement is performed.

60. (Previously presented) The method of claim 58, wherein referencing the cutting guide

includes positioning a pin into the bone to secure the cutting guide to the bone and wherein the

pin position is determined by the alignment guide.

61. (Previously presented) The method of claim 58, wherein the guide surface has a width

less than the width of the cut portion of the bone.

62. (Previously presented) The method of claim 58, wherein the joint is selected from the

group consisting of: finger, wrist, elbow, shoulder, spine, hip, knee, ankle, toe.

63. (Previously presented) The method of claim 58, wherein at least a portion of the

articulating surface of the joint is replaced within the cut bone.

64. (Previously presented) The method of claim 63, wherein the at least a portion of the

articulating surface is replaced with a material selected from the group consisting of: biological,

metal, composite, polymeric, ceramic, metal/ceramic, metal/polymer, polymer/ceramic,

polymer/polymer, ceramic/ceramic, and ceramic/composite.

65. (Previously presented) The method of claim 58, wherein the joint has a plurality of

articulating surface compartments, and at least a portion of the articulating surface is not

replaced in all articulating surface compartments.

66. (Previously presented) The method of claim 58, wherein the cutting guide or the

alignment guide is passed into the body through a cannula.